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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,372	01/15/2004	Herbert E. Schwartz	26502-73682	5422

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/758,372	**Applicant(s)** SCHWARTZ ET AL.
	Examiner Julian W. Woo	**Art Unit** 3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _26 March 2008_.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-4 and 6-17_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-4 and 6-17_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Colvin et al. (6,066,160). Colvin et al. disclose, at least in figures 1-5, a device including a first anchor (30) having a locking mechanism (e.g., 20 or 92) configured to grip and hold a suture at any point along the suture and a cannula (e.g., 12 or 72) including a lumen (14A or 14B), a second anchor (40) having a hole, and a suture (16), where the suture connects and first and second anchors by passing through the lumen of the cannula of the first anchor (at 14A) while traveling in a first direction, by passing through the hole of the second anchor, and by returning through the lumen of the cannula of the first anchor (at 14B) while traveling in a second and opposite direction, and where the first anchor is shaped (a circular, disc-shape) to seat below a first surface of a meniscus. Note: The introductory statement of intended use ("for repairing a defect in soft tissue" or a meniscus) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Colvin et al., which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 10-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golds et al. (5,383,905) in view of Pierce (4,823,794). Golds et al. disclose the invention substantially as claimed. Golds et al. disclose, at least in the figures; a device usable for repairing a defect in soft tissue, where the device includes a first anchor (10) having a locking mechanism (12 and/or 16) and a single lumen (22); and a suture coupled to the first anchor, the suture passing through the lumen of the first anchor, wrapping around tissue and returning through the lumen of the first anchor, and where tension on the suture is adapted to pull tissue portions together and the locking mechanism locks the suture in place, where the locking mechanism is configured to grip and hold suture, and where the suture forms a loop with respect to the first anchor.

However, Golds et al. do not disclose a second anchor with at least one hole, where the second anchor includes first and second holes. Pierce discloses, in figures 1-5; an anchor (10, 62, or 60) with first and second holes (in anchor 10 or 62) used in joining tissue portions together and used with a loop of suture, where the suture passes through the first hole in first direction and returns through the second hole in a direction opposite the first direction (see fig. 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Pierce, to apply a second anchor with the device of Golds et al. Such an anchor (i.e., a pledget) would distribute the tension of a suture over a broad area of tissue and thus lessen the risk of trauma to the tissue from the suture and/or the first anchor. Note: The introductory statement of intended use ("for repairing a defect in soft tissue" or a meniscus) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Golds et al., which is capable of being used as claimed if one desires to do so.

5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golds et al. (5,383,905) in view of Pierce (4,823,794), and further in view of Morell (3,952,377). Golds et al. in view of Pierce disclose the invention substantially as claimed, but do not disclose that the lumen of the first anchor has first and second openings, where the first opening is larger than the second opening, or where the lumen is tapered. Morell teaches, at least in figures 2 and 3 and in the abstract, an anchor with a lumen (10) that has first and second openings, where the first opening (at the top of the lumen as shown in the figures) is larger than the second opening (at the bottom of

the lumen), or where the lumen is tapered. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Morell, to modify the lumen of the device of Golds et al. in view of Pierce, so that it has a first opening larger than a second opening as claimed or so that it is tapered. Such a modification would ensure secure gripping of the suture by the first anchor when the device and suture are deployed.

Response to Amendment

6. Applicant's arguments filed on March 26, 2008 and with respect to claims 1-4 and 6-9 have been fully considered but they are not persuasive: See the restatement of the rejection above. That is, Colvin et al. indeed disclose passing a suture through the first anchor lumen (14A) while traveling in a first direction, by passing through the second anchor hole, and by returning through the first anchor lumen (14B) while traveling in a second and opposite direction. For example, in figure 4, the suture (16) forms a U-shape as it is passed through holes of the first and second anchors, where one leg of the suture is passed from the first anchor (10) to the second anchor (40) in one direction, and then another leg of the suture is passed from the second anchor to the first anchor in a second and opposite direction. Moreover, figures 5 and 7 disclose arrow markings on suture 76, which show the opposing directions of legs of the suture as they are passed through a first anchor.

Applicant's arguments with respect to claims 10-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

June 29, 2008